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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,992	MAILLERE ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-64* is/are pending in the application.

4a) Of the above claim(s) *27, 29, 31, 34-56 and 59-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,28,30,32,33,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 4/19/2010. Claims 26, 28, 30, 32, 33, 57 and 58 are under current examination. It is noted that claim 27 requires the presence of a third peptide and thus, this claim and its dependent claims are withdrawn in view of the restriction and applicant's election of species.

Note, while searching for the elected species, art was found that reads upon the generic claims and has been cited herein in the rejection(s) below for reasons of compact prosecution. However, this should not be construed that the search has been extended for the entire scope of all the species encompassed by the instant claims.

Election/Restrictions

Claims 27, 29, 31, 34-56 and 59-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/19/2010.

Applicant's election with traverse of Group I in the reply filed on 4/19/2010 is acknowledged. The traversal is on the ground(s) that Groups I, II and III should be grouped together because the peptide of Group I is made using the nucleic acid of Group II and the method of Group III is performed with the peptide mixture of Group I.

This is not found persuasive because a peptide and a nucleic acid are structurally different, comprising either amino acids or nucleic acids. Thus, given the correlation between structure and function, a peptide and a nucleic acid have different functions. Separately, the peptide mixture of Group I and the method of using such

peptides Group III for evaluating an immune state of an individual are distinct inventions because the peptide mixture of Group I may be used in other materially different methods, including inducing an immune response. Note that the peptides of Group I are not limited to those made by the nucleic acids of Group II, as these peptides are only limited by function. Note that claim 42 is dependent on claim 41 and not base claim 26 for the claimed peptides. There are no specific sequences in the claims of the Group I peptides that correlate with the nucleic acids or vice versa. The peptides of Group I can be used in materially distinct methods as those of Group III, such as, *in vitro* assays, treatment of hepatitis C, etc., see WO 95/27733 (IDS filed 2/2/2005). Applicant's suggestion of rejoinder when applicable is acknowledged.

Applicant's election without traverse of species: C peptide 27-51, NS3 peptide 1524-1553, CD8+ epitope, NS3 CD8+ epitope and NS3 1538-1552 in the reply filed on 4/19/2010 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

See p. 33 of the instant specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26, 28, 30, 32, 33 and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a peptide mixture comprising peptides derived from the HCV, wherein the peptides are derived from the C protein and/ or the NS3 protein. As claimed, it is not clear how the peptide mixture is distinguished from that comprised by blood. See p. 5 of the instant specification which discloses that T epitope peptides are the result of proteolytic degradation of the antigens by the APC and they are variable in length (13-25 amino acids). Thus, the claims appear to read on a peptide mixture found in nature. Separately, claim 57 is drawn to a peptide that may be found in nature. It is suggested that the claims are amended to read on a peptide mixture comprising isolated and purified peptide(s) or an isolated and purified peptide (for claim 57).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28, 30, 32, 33, 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 26 and 57 read on a peptide or mixture thereof wherein the peptide(s) binds "to at least four different HLA II molecules whose allelic frequency is greater than 5%". As claimed, it is not clear whether the four different HLA II molecules represent four different types of molecules (e.g. HLA-DR1 or HLA-DR3) or four different molecules of the same type (e.g. all 4 are HLA-DR1 molecules). The dependent claims fall herein.

Appropriate correction is required.

For the purposes of this action, and in accordance with the teachings as provided on p. 12, lines 14+, the claims are interpreted as a peptide that binds to four different types of HLA II molecules.

Claims 26, 28, 30, 32, 33, 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 26 is treated as a representative of the rejected claims. The claims are drawn on a peptide mixture comprising at least two different peptides derived from the HCV, at least one of which is a peptide derived from the C protein that binds to at least 4 different types of HLA II molecules whose allelic frequency is greater than 5% in the Causasian population with a binding activity of <1000 nM. Also, see claim 27 which is drawn to a peptide mixture comprising at least two different peptides derived from HCV, at least one of which is a peptide derived from the NS3 proteins that binds to at least 4 different types of HLA II molecules whose allelic frequency is greater than 5% in the Causasian population with a binding activity of <1000 nM. The claims therefore read on a genus of peptides (derived from both C and NS3 proteins of HCV) which have been identified by specific functional characteristics.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

The claims are rejected on multiple grounds.

The claims are rejected for lacking adequate descriptive support with respect to peptides of either the C protein or NS3 protein that binds to at least 4 different types of HLA II molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of <1000 nM. Structurally, the claims are drawn to any and all peptides with the claimed functional characteristics. However, applicants have only identified a small number of epitopes (see Figures 2 and 3 of appl.). Also, it is not

clear from the instant specification if peptide 27-51 of the core protein (the elected species) meets the specific functional limitations as claimed. Thus, while the applicant has identified some epitopes that are able to bind at least 4 different types of HLA II molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of <1000 nM, there does not appear to be a sufficient number of examples to demonstrate that the applicant is in possession of *every* HCV epitope (including the elected species, peptide 27-51 of the core protein) that meets the functional limitations as claimed. Thus, the applicant has not provided a sufficient number of examples to demonstrate possession of any combination of peptides that binds at least 4 different types of HLA II molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of <1000 nM.

Further, the application nowhere provides any correlation between any non-functional characteristic of a group of peptides to their ability to bind to 4 different type of HLA molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of <1000 nM. Note that there is no apparent similarity between the various peptides identified by the applicant as to meet the claimed functional characteristics. The specification discloses peptides derived from HCV that are defined by function, namely their binding to at least four different HLA II molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of ,100nm. However, neither the specification nor the general knowledge of those skilled in the art provide evidence of any partial structure which would be expected to be common to the members of the genus. There is great diversity within HLA class II antigens, as

this includes HLA-DR, HLA-DQ, HLA-DP, etc. Thus there is a lack of a structural relationship between the proteins of HCV and HLA II molecules.

Also, the claims read on peptides "derived from" the hepatitis C virus; see claim 26 as a representative example. Note that such derivatives include modifications of structures, including substitutions; see [0042] of the instant specification. The specification, however, fails to provide, for example, what modifications of the peptides would still lead to their ability to be recognized in order to induce an immune response. Note that modifications to the peptide may result in the loss of function in inducing an immune response or binding to the HLA II molecules as required by the instant claims and there is uncertainty in the functional effects of such modifications. The instant specification fails to provide any structure to function correlations which would support the scope of a peptide "derived from" the HCV. It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities.

It is known in the art that the substitution of some amino acids within the protein sequence may cause the loss of function of the protein. Thus, the large number of sequences encompassed by the current claims may or may not be effective in modulating the TRAF mediated signal transduction. See the following publications that support this unpredictability (Baker et al., Protein Structure Predication and Structural Genomics, Science (2001) Vol. 294, No. 5540, pages 93-96; Attwood, T. The Babel of Bioinformatics, Science (2000) Vol. 290, no. 5491,

pages 471-473). The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed and there is inadequate descriptive support for any peptide mixture comprising any peptide "derived from" HCV proteins that would induce anti-HCV immune responses.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by members of the genus, because HCV proteins are not representative of the claimed genus.

Claims 26, 28, 30, 32, 33, 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an HCV immunogenic composition comprising a peptide mixture wherein the peptides are of defined structures, does not reasonably provide enablement for a peptide mixture wherein the peptides are "derived from" HCV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. The claim is drawn to a vaccine which comprising an immunogenic composition.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C 112 ¶, the courts have put forth a series of factors. The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The claims are drawn to a peptide mixture wherein the peptides are derived from a hepatitis C virus and such a genus includes modifications, such as substitutions; see para. 42 and instant claim 32. The specification, however, fails to provide, for example, what modifications of the peptides would still lead to their ability to be recognized in order to induce an immune response. Note that modifications to the peptide may result in the loss of function in inducing an immune response or binding to the HLA II molecules as required by the instant claims and there is uncertainty in the functional effects of such modifications. The instant specification fails to provide any structure to function correlations which would support the scope of a peptide "derived from" the HCV.

It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different

biological or pharmacological activities. It is known in the art that the substitution of some amino acids within the protein sequence may cause the loss of function of the protein. Thus, the large number of sequences encompassed by the current claims may or may not be effective in modulating the TRAF mediated signal transduction. See the following publications that support this unpredictability (Baker et al., Protein Structure Predication and Structural Genomics, Science (2001) Vol. 294, No. 5540, pages 93- 96; Attwood, T. The Babel of Bioinformatics, Science (2000) Vol. 290, no. 5491, pages 471-473). The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one of ordinary skill in the art at the time the invention would not have recognized what modified peptides could be successfully used. The instant specification is not enablign for any peptide mixture comprising any peptide "derived from" HCV proteins that would induce anti-HCV immune responses.

In view of the teachings of the prior art describing a lack of vaccines for HCV and the unpredictability of the art and the lack of a correlation between the claimed peptide mixtures and a successful vaccine, the ordinary artisan would not be able to make or use the full scope of claims without much undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Godkin, WO 02/34770 (IDS filed 2/2/2005).

The claims are drawn to (in part): a peptide mixture comprising at least 2 different peptide derived from HCV, at least one of which is derived from the C protein or at least one which is derived from the NS3 protein, that binds to at least 4 different HLAII molecules whose allelic frequency is greater than 5% in the Caucasian population with a binding activity of <1000 nM.

Godkin discloses a peptide mixture comprising one or more peptides derived from HCV, wherein at least one may be derived from the core protein wherein the peptides bind to HLA-DR11 and HLA-DR12 (see abstract); note that these HLA epitopes are strongly associated with the Caucasian population, as can be seen by the instant claims, including claim 2. The peptides may be selected from various regions between amino acids in the core region (e.g., 31-45) and the NS3 region; see page 5. The author teaches that the peptides may be up to 100 amino acids in length. Given that Godkin discloses one or more copies of peptides and selected from various regions of HCV, it would be expected that these would be capable of binding four HLA-DR molecules as well as meeting any other functional limitations of the instant claims. The same compositions must have the same properties. Godkin discloses that the peptides mixtures are used in various pharmaceutical compositions, including immunogenic compositions, etc which comprise a pharmaceutical carrier, an adjuvant, and a

liposome; see pages 18, disclosing liposomes and 31-38, disclosing pharmaceutical carrier and adjuvants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26, 28, 30, 32, 33, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godkin, WO 02/34770 (IDS filed 2/2/2005) in view of Berzofsky, WO 95/27733 (IDS filed 2/2/2005), Hoffman (*Hepatology*, 1995-attached), Hiranuma (*J. Gen. Virology*, 1999-attached) and US Patent 6692751 (hereinafter as "Zebedee").

Godkin is addressed above. The author teaches a peptide mixture comprising different peptides from both the C and NS3 protein of HCV, wherein such peptides may be extended to 100 a.a. in length.

While Godkin teaches that the peptides may be selected from various regions between amino acids in the core region (e.g., amino acids 31-45) and the NS3 region (e.g., amino acids 1207-1221), Godkin fails to specifically disclose applicant's elected species of amino acids within the core, a peptide comprising 27-51, and the NS3, a peptide comprising 1524-1553. Also, Godkin does not disclose using C and NS3 proteins of HCV genotype 1 (see claim 38) or a peptide mixture in the form of a single fusion protein (see claim 41). While Godkin teaches the use of the peptide as a

diagnostic reagent (p. 11, para. 4), the author does not disclose that such a reagent is labeled (see claim 58).

Berzofsky teaches core peptides that provide binding motifs for human HLA antigens; see abstract.

Hoffman teaches the core protein ranges from amino acids 1-115 and that the NS3 region ranges from 1007-1534; see abstract and page 633. Note that the authors provide proteins derived from the genotype 1a strain, meeting the limitation of claim 38 (see p. 633, col. 1). Hoffman also teaches core protein, 23-42, which meets the limitation of claim 32b wherein the "peptides comprising less than the entire sequence of the peptides as defined in a) and including at least 11 consecutive amino acids of the preptides as defined in a)", given a peptide of a) includes peptide 27-51 (the elected species). Note that this teaching of peptide 23-42 also meets the structural limitations of claim 33 in that this protein comprises amino acid positions 27-41.

Hiranuma discloses using compositions to induce an immune response in a subject, wherein the composition comprises conjugated peptides comprising different HCV epitopes (see abstract and instant claim 41). The author notes that the fused form of epitopes resulted in greater cytotoxic activity than immunization with the epitopes in independent forms (see abstract).

Zebedee discloses HCV antigens for detection of antibodies against the antigens (see abstract), wherein the antigen is labeled with biotin etc (see col. 4, l ines 21+).

It would have been obvious to one of ordinary skill in the art to have employed peptides within the amino acid ranges of applicant's elected species, given that Godkin

teaches the use of peptides from both the core and NS3 which may be extended to having up to 100 amino acids in length, and Berzofsky provide a generic disclosure that portions of the core protein bind HLA molecules. Hoffman teaches that the regions of the core protein and NS3 are *known* structures with regions of a limited number of amino acids. One of ordinary skill in the art would have been motivated to look at different amino acids sequences that bind HLA-DR and other HLA II molecules given the prior art as a whole teaches that numerous peptides within the limited regions of the core and N3S proteins provide HLA binding molecules with a multitude of diagnostic and therapeutic uses.

It would have been obvious to one of ordinary skill in the art to use a fusion protein in the methods disclosed by Godkin. One of ordinary skill in the art would have been motivated to use the peptide mixture in a form of a single fusion peptide, given Hiranuma provides that such a peptide results in greater cytotoxic activity.

It would have been obvious to one of ordinary skill in the art to incorporate a label in the diagnostic reagent taught by Godkins. One of ordinary skill in the art would have been motivated to do so for the advantage of amplifying the reagent's signal for detection.

One of ordinary skill in the art would have a reasonable expectation of success given the structure of the core and the NS3 regions are known and the established correlation of various peptides within the core and NS3 region provide the expected function of binding HLA molecules. Separately, there would have been a reasonable expectation of success given the underlying techniques are widely known and

commonly used as shown by the applied prior art (e.g. creating conjugated proteins, or labeling a diagnostic reagent, etc.).

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Note that given the structural limitations of the peptides are met in view of the prior art, the functional limitations must also be met because a composition and its properties are inseparable.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648